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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,098	10/27/2003	Devdutt Chaturvedi	Q74941	8458

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EXAMINER

POWERS, FIONA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/693,098

Applicant(s)

CHATURVEDI ET AL.

Examiner

Fiona T. Powers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56, 58-77 and 79-97 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24, 27 and 29-55 is/are allowed.
- 6) ☒ Claim(s) 3, 56, 59-77 and 80-97 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 4-23, 25-28, 58 and 79 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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Receipt is acknowledged of the amendment filed June 17, 2005, which has been entered in the file.

Claims 1, 2, 25, 26, 28, 58, 79 and 83 are objected to because of the following informalities: in claims 1 and 2 "naphthyloxy" should be -Naphthyloxy-. In claims 2, 25, 58, 79 the period after compound (xxi) should be deleted. In claims 24 and 56 "Wherein" should be -wherein-. In claim 26 and 28, "Hexamethylphosphoric" should be -hexamethylphosphoric-. In claim 58 the "/" at the end of the claim should be replaced by a period. In claim 83, in "-oral" the dash should be deleted. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 56, 58 to 77 and 79 to 97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of cardiovascular disorders and hyperglycemic condition (diabetes) and compounds and pharmaceutical compositions for such use, does not reasonably provide enablement for prevention of hyperglycemic condition (diabetes) and compounds and pharmaceutical compositions for the

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prevention of hyperglycemic condition (diabetes). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph are as follows:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of skill in the art.

See *In re Wands*, 8 USPQ2d 1400.

The nature of the invention is the treatment and prevention of cardiovascular disease and hyperglycemic condition (diabetes) and compounds and pharmaceutical compositions for such use.

The state of the prior art is that there is no support for the prevention of hyperglycemic condition (diabetes) and for compounds and pharmaceutical compositions for the prevention of hyperglycemic condition (diabetes) as the etiology of this

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disease is not known or clearly defined. Flanders et al. (Autoimmunity, 29(3), 235-246, 1999) teaches that "despite recent progress in immunology and genetics, the causes of type 1 diabetes remain unknown. Prevention of autoimmune diseases through immunomodulation or gene therapy has not yet been successful in humans." (abstract) "The public health answer to the prevention of IDDM is to continue to research and wait for more information." (page 243) In further support that there is no current prevention for diabetes, Rosenbloom et al. (Clinical Pediatrics, Feb 1988, 37, 2, 143-152) teach that "Secondary prevention emphasizes the reversibility of many of the metabolic changes that characterize NIDDM, particularly with weight control and increased physical activity, but the clinical evidence that this is achievable for extended periods of time in any population is not available." (page 151) The specification provides not supportive teaching the compounds of the invention would be able to successfully prevent hyperglycemic condition (diabetes) where the etiology is unknown. Thus and undue amount of experimentation is needed by one of ordinary skill in the art to prevent hyperglycemic condition (diabetes).

This rejection can be overcome by deleting "and prevention" or "or prevention" from the claims.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 56, 59 to 77 and 80 to 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Albright et al. (US 4260816), of record.

The reference discloses the claimed pharmaceutical compositions that contain compounds of the formula I where  $R_1$ ,  $R_2$  and  $R_3$  are hydrogen and  $R_4$  is substituted phenyl and the claimed method of treating or preventing cardiovascular disorders, hyperglycemia and diabetes with the compounds. Note the first two compounds listed in Table I, Examples 3, 4, 7 and 11 and column 1, lines 20 to 44, column 2, lines 16 to 33 and 40 to 48 and column 4, line 9 to column 5, line 44.

This rejection can be overcome by deleting "substituted phenyl" from the definition of  $R_3$  and  $R_4$ .

Applicant's arguments filed June 17, 2005 have been fully considered but they are not persuasive. The rejection of claim 1 over Albright et al has been withdrawn since claim 1 has been amended to delete substituted phenyl from the definition of  $R_3$  and  $R_4$ . However, the amendments to claims 56 and 77 do not overcome the rejection over Albright et al.

Claims 4 to 23, 58 and 79 are objected to as being dependent upon a rejected or objected to base claim, but would

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be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 24, 27 and 29 to 55 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Monday - Friday 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Fiona T. Powers*  
Fiona T. Powers  
Primary Examiner

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August 24, 2005